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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/096,593	06/12/98	O'CONNOR	A-64559-3/RT

HM22/0523

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EXAMINER

COOK, L

ART UNIT	PAPER NUMBER
1641	19

DATE MAILED: 05/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. 09/096,593	Applicant(s) O'CONNOR ET AL.	
	Examiner Lisa V. Cook	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 May 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18, 20, 22-23, and 25-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18, 20, 22-23, and 25-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- |   |  |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Examination***

1. The request filed on 4/3/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/096,593 is acceptable and a CPA has been established. An action on the CPA follows.
2. Claims 18, 20, 22, 23, and 25-30 are pending and currently under consideration.

## **OBJECTIONS MAINTAINED**

### ***Drawings***

3. Applicants have deferred the corrective action, eliminating defects in the drawings cited by the Draftsperson under 37 CFR 1.84 or 1.152 on PTO-948. However, formal correction of the noted defect can be deferred until the application is allowed by the examiner.

### ***Information Disclosure Statement***

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on PTO-1449 has cited the references they have not been considered.

***Specification***

5. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

6. The use of several trademarks is noted in this application. They should be capitalized wherever they appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks. (For example, see page 26 – Teflon®).

7. The disclosure contains several drawing on pages 14-20 and 22-33 it is noted that the drawing should be submitted to the office as required by 37 CFR 1.81.

**REJECTIONS WITHDRAWN**

***Double Patenting***

**8. Double patenting obviousness-type rejection:**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6,096,273. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions are drawn to electrodes having monolayers and conductive oligomers for analyte detection. The instant claims are directed to non-nucleic acid analytes while the patent of Kayyem et al. is directed to nucleic acid analytes. However, it would have been obvious to the skilled practitioner in the art to employ other analyte binding entities (any ligand binding pair) in the coated apparatus to detect other unknown compositions because differences in the type of electron donor/acceptor moieties, electron transfer mediators and in the configuration, would have been known to one of ordinary skill in the art to be variable and discretionary.

9. Provisional double patenting rejection: obviousness-type

Claims 18-28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-40 of copending Application No. 08/873,597. Although the conflicting claims are not identical, they are not patentably distinct from each other because both patent applications are drawn to an apparatus comprising electrodes with conductive oligomer and monolayers. The differences are in the analyte being detected.

The instant invention detects non nucleic acid targets, wherein copending application no. 08/873,597 detects nucleic acids. This difference in the presence or configuration of the combination of a nucleic acid probe or another target sequence with the instant invention would have been known to one of ordinary skill in the art to be variable and discretionary based on experimental design and desired results.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Terminal Disclaimer***

The terminal disclaimer filed on 4/3/01 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of Patent # 6,096,273 has been reviewed and is accepted. The terminal disclaimer has been recorded. Therefore the double patenting rejections are withdrawn.

**REJECTIONS MAINTAINED**

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

*Please note: the rejections set forth are maintained because they can not be overcome by a Terminal Disclosure. See MPEP 804.02.*

*Rejections over a patent or another copending application based on double patenting or 35 U.S.C. 103(a) are similar in the sense that both require comparison of the claimed subject matter with at least part of the content of another patent or application, and both may require that an obviousness analysis be made.*

*One significant difference is that a double patenting rejection must rely on a comparison with the claims in an issued or to be issued patent, whereas an obviousness rejection based on the same patent under 35 U.S.C. 102(e)/103(a) relies on a comparison with what is disclosed (whether or not claimed) in the same issued or to be issued patent. In a 35 U.S.C. 102(e)/103(a) rejection over a prior art patent, the reference patent is available for all that it fairly discloses to one of ordinary skill in the art, regardless of what is claimed. In re Bowers, 359 F.2d 886, 149 USPQ 570 (CCPA 1966).*

*A second significant difference is that a terminal disclaimer cannot be used to obviate a rejection based on 35 U.S.C. 102(e)/103(a) prior art. In re Fong, 378 F.2d 977, 154 USPQ 25 (CCPA 1967). The purpose of a terminal disclaimer is to obviate a double patenting rejection by removing the potential harm to the public by issuing a second patent, and not to remove a patent as prior art.*

11. Claims 18, 20, 22, 23, and 25-30 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 08/873,597 which have a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future patenting of the conflicting application.

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

I. Claims 18, 20, and 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keen (U.S. Patent #6,060,327) in view of Kossovsky et al. (U.S. Patent #5,585,646) and in further view of Wohlstadter et al. (U.S. Patent #6,090,545).

Keen discloses sensors to detect an analyte without mediators. The sensors have a plurality of conductive polymer strands attached to a plurality of molecular recognition head groups (having affinity for an analyte) which are attached to an electrode substrate. The conductive polymer strands maybe multi-stranded nucleic acids, electron transport proteins, synthetic organic and inorganic conducting polymers, metal crystallite molecular wires, and Langmuir-Blodgett conducting films. (see column 7, lines 44-63).

Keen (U.S. Patent #6,060,327) differs from the instant invention in failing to specifically teach self-assembled monolayers and an array of first measuring electrodes in their device designs.



However, Kossovsky et al. disclose improved bioelectronics devices in comprising a layer of a polyhydroxy oligomer that is spaced between the surface of a semiconductive material (applicant's monolayer) and an electronically active biochemical molecule (applicant's binding ligand) which is bound to the semiconductive surface of an electronic device (applicant's electrode). The layer of polyhydroxy oligomer functions as a biochemical stabilization layer to prevent denaturation of the electronically active biochemical molecule (Abstract). The stabilization layer is made up of one or more polyhydroxy oligomers. Exemplary polyhydroxy oligomers include carbohydrates, carbohydrate derivatives, and other macro molecules with carbohydrate like components.

Kossovsky et al. further teach that the surface modification concept and the electron donor-acceptor concept can be combined at the semiconductor surface and utilized in various methods. Specifically cited is the method of Colvin et al. (Column 4, Lines 12-25). Colvin et al. Construct devices by attaching semiconductor nanocrystals to metal surfaces using self assembled monolayers as bridging compounds.

While, Wohlstadter et al. disclose patterned, multi-array multi-specific surfaces on a support (PMAMS) that are electronically excited in electrochemiluminescence based tests. The PMAMS can be generated from self- assembled monolayers on a surface. (column 13, lines 10-31).

Keen (U.S. Patent #6,060,327), Kossovsky et al. (U.S. Patent #5,585,646), and Wohlstadter et al. (U.S. Patent #6,090,545) are analogous art because they are from the same field of endeavor, all three inventions teach the fabrication/utility of electrochemical biosensors.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the self assembled monolayers taught by Kossovsky et al. in the method of Keen to perform analyte detection in an affinity assay system because such self assembled monolayers as taught by Kossovsky et al. are well known in the art. A person of ordinary skill in the art would have had a reasonable expectation of success utilizing such materials, because Kossovsky et al. disclosed that the use of self assembled monolayers allows the molecules to be held in a specific orientation with respect to the metal and are applicable in many system designs (Column 4, Lines 12-25).

recent advances have extended self assembled monolayers beyond the prototype gold/thiol systems. Fatty acids on aluminum, silanes on silicon, isonitriles on platinum and rigid phosphates on metals are all examples.

Kossovsky et al. also teach the use of the any denaturization of the biochemical material which might be caused by the semiconductor material is eliminated or substantially reduced by placing the stabilization layer of polyhydroxy oligomers between the biochemical material and the semiconductor (Column 7, Lines 13-18).

Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to multi-electrode arrays as taught by Wohlstadter et al. in the method of Keen in view of Kossovsky et al. to perform analyte detection in an affinity assay system because such multi-electrode arrays as taught by Wohlstadter et al. are well known in the art. A person of ordinary skill in the art would have had a reasonable expectation of success utilizing at least two measuring electrodes, because Wohlstadter et al. disclosed that the use of multi-electrode arrays allows for the simultaneous assay of a plurality of analytes in a single sample. (Column 3, lines 36-39).

One of ordinary skill would have been motivated to do this because Wohlstadter et al. taught that their invention reduced the time and cost associated with individual analyte assays. (column 3, lines 33-35).

**II.** Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keen (U.S. Patent #6,060,327) in view of Kossovsky et al. (U.S. Patent #5,585,646) and in further view of Wohlstadter et al. (U.S. Patent #6,090,545) as applied to claims 18, 20, 25-30 above and further in view of Meade (U.S. Patent #6,013,459).

See previous discussion of Keen (U.S. Patent #6,060,327) in view of Kossovsky et al. (U.S. Patent #5,585,646).

Keen and Kossovsky et al. differ from the instant invention in not specifically teaching the conductive oligomer formulas exemplified in claims 22 and 23.

However, Meade teaches methods of detecting analytes utilizing electron transfer. The invention involves an electrode covalently attached to a redox active complex. The complex includes a binding ligand. The particular apparatus for detection has a test chamber comprising a first measuring electrode, a second measuring electrode an AC/DC voltage source electrically connected to the test chamber, and an optical signal processor for detection. (column 2, lines 4-20). In one embodiment the redox active complex is attached to an electrode via a conductive oligomers that are the same oligomers structures of the instant invention, specifically claims 22 and 23. (see column 8 and column 12).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the oligomers structures as taught by Meade in the method of Keen (U.S. Patent #6,060,327) in view of Kossovsky et al. (U.S. Patent #5,585,646) to perform analyte detection in an affinity assay system because such oligomers as taught by Meade are well known in the art. A person of ordinary skill in the art would have had a reasonable expectation of success utilizing these structures, because Meade disclosed that these structures were suitable for sensory embodiments and analyte detection. (i.e. column 7, lines 16-45).

One of ordinary skill would have been motivated to do this because Meade taught that their inventive oligomers resulted in high conductivity, exhibited sufficient solubility in organic solvents and/or water, and were chemically resistant to assay reactions. (column 8, lines 1-7).

12. For reasons aforementioned, no claims are allowed.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 308-4242, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (703) 305-0808. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

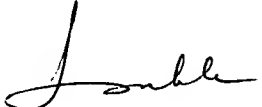
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Lisa V. Cook*  
*Patent Examiner*  
*Art Unit: 1641*  
*CM1 7B17*  
703-305-0808

  
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05/21/01